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AMENDMENT AND RESPONSE

### REMARKS

By the present amendment, Applicants amend claims 26 and 29. With this amendment, claims 26-37 are pending in this application. No additional fees are believed due; however, the Commissioner is authorized to debit deposit account no. 11-0855 for any deficiency in fees.

#### **I. 35 U.S.C. § 102 Rejections**

The Action rejects claims 26-35 as being anticipated by U.S. Patent No. 4,982,730 to Lewis, U.S. Patent No. 5,172,692 to Kulow et al., and U.S. Patent No. 5,413,550 to Castel. Applicants respectfully traverse this rejection and ask that it be withdrawn.

Claims 26 and 29 both recite a method for promoting wound healing by emitting ultrasonic waves that contact the wound. Claim 26 recites emitting ultrasonic waves from a transducer and directing at least some of those waves toward a surface of the body capable of reflecting ultrasonic waves. Claim 26 also recites reflecting at least some of the ultrasonic waves off the body surface and toward the wound. Claim 26 has been amended to clarify that at least some of those reflected waves contact the wound and promote healing thereof. The amendments to claim 26 are fully supported by the specification as originally filed at page 11, line 7 to page 13, line 2 and by Figure 1, *inter alia*.

Claim 29 recites emitting ultrasonic waves from a transducer such that at least some of those waves contact the wound and promote healing thereof. Claim 29 also recites directing ultrasonic waves emitted from the transducer toward an area offset from the axis of the transducer. Claim 29 has been amended to clarify that waves that contact and heal the wound are waves that are directed toward an area offset from the axis of the transducer. None of the references relied upon by the Action teach or suggest at least independent claims 26 and 29.

#### **A. Castel**

Castel teaches an apparatus for controlling the "dosage" of ultrasonic treatment (e.g., the intensity and time of treatment) depending on the type and location of tissue to be treated and the desired effect of such treatment. Nothing in Castel teaches or suggests treating the desired tissue in any way other than by impinging the ultrasonic waves directly on the tissue. There is certainly no teaching or suggestion of directing ultrasonic waves toward a surface of the body for reflecting at least some of the ultrasonic waves off of the body surface and toward the wound, as recited in claim 26. Nor is there teaching that such reflected waves contact the wound

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for healing, as recited in claim 26. Moreover, nothing in Castel teaches or suggests directly the ultrasonic waves anywhere but directly along the axis of the transducer from which they are being emitted. Castel does not teach or suggest directing ultrasonic waves toward an area offset from the axis of the transducer or that such waves contact the wound for healing, as recited in claim 29.

The Action acknowledges this lack of disclosure in Castel by relying upon the principle of inherency to conclude that the "reflection of waves and the angular offset toward a wound would be inherent in the use of the device on a patient in that both skin/tissue and bone present in the patient would inherently cause such reflections and change in direction of at least some of the ultrasonic waves." Action, p. 2. However, the Action's resort to the inherency doctrine is misplaced. To establish inherency, the Action must demonstrate that use of the Castel device *necessarily functions* to direct ultrasonic waves toward a body surface that reflects the waves toward the wound and that such reflected waves contact the wound for healing (as recited in claim 26) and/or to direct ultrasonic waves emitted by the transducer toward an area offset from the axis of the transducer such that such waves contact the wound for healing (as recited in claim 29). See *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999) ("if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates"); see also *Ex parte Levy*, 17 U.S.P.Q. 1461, 1464 (U.S.P.Q. 1990) ("In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.") (emphasis in original). "Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1990).

The Action has failed to make the requisite showing that the Castel device must necessarily function in the manner recited in claims 26 and 29. Moreover, these necessary showings are impossible to establish. It is untrue, as the Action maintains, that bone or skin in the patient will always "cause [] reflections and change in direction of at least some of the ultrasonic waves." Action, p. 2. This is only arguably true if waves are available for reflection by the bone or skin. However, the Castel device can be used to treat tissue with ultrasonic waves by emitting waves that travel along the axis of the transducer to impinge tissue that is directly in

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the path of such waves. Because all of the waves are directed onto the desired tissue, no waves are available for reflection by bone or tissue. Indeed, this is the most obvious intended use of the Castel device from a fair reading of Castel. Moreover, even assuming, *arguendo*, that wave reflection did occur with use of the Castel device, such waves would not necessarily be reflected toward the wound or to contact the wound so that the reflected waves promoted wound healing, as recited in claim 26. Similarly, even assuming, *arguendo*, that use of the Castel device resulted in waves being directed toward an area offset from the transducer axis, such waves would not necessarily contact the wound to promote healing, as recited in claim 29.

Thus: (1) no directing of waves toward a surface of the body capable of reflecting ultrasonic waves and reflection of waves off of that body surface toward the wound so that the reflected waves contact and promote healing of the wound and (2) no directing of waves in a direction offset from the transducer axis so that such waves contact a wound and promote healing need occur to accomplish the intended goals of the Castel device. Because the Castel device does not necessarily function to perform the methods recited in claims 26 and 29, the limitations recited in claims 26 and 29 are not inherently present in Castel and Castel does not anticipate these claims.

**B. Kulow et al.**

Kulow teaches a device for imparting mechanical energy impulses to a wound to reduce the swelling, redness, and inflammation of the wound. Kulow discloses substituting ultrasonic energy for the mechanical energy and touts ultrasound for the ability "to accurately select a tissue target area for treatment." Kulow, col. 5, lines 63-68. However, Kulow provides absolutely no disclosure of the device to be used for emitting ultrasound. Rather, the limited disclosure of Kulow at most teaches merely impinging tissue with ultrasonic waves.

As with Castel, there is absolutely no teaching or suggestion of directing ultrasonic waves toward a surface of the body capable of reflecting ultrasonic waves, nor of reflecting at least some of the ultrasonic waves off of the body surface and toward the wound such that the reflected waves contact and promote healing of the wound, as recited in claim 26. Nor is there a teaching or suggestion of directing ultrasonic waves towards an area offset from the transducer axis such that some of the directed waves contact and promote healing of the wound, as recited in claim 29. The Action again resorts to the doctrine of inherency to supply these missing claim limitations, and again use of this doctrine is inappropriate. The complete lack of disclosure in

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Kulow of any device for emitting ultrasonic waves renders it impossible for the Action to establish that use of this imaginary device would necessary function to perform the limitations recited in claims 26 and 29. Indeed, with Kulow's limited disclosure of merely impinging desired tissue with ultrasound, any ultrasonic device could certainly accomplish this function by emitting waves that travel along the axis of the transducer to impinge tissue that is directly in the path of such waves. No directing of waves toward a surface of the body capable of reflecting ultrasonic waves and subsequent wave reflection by the body surface toward a wound (claim 26) and no wave path directed offset from the transducer axis (claim 29) must necessarily occur. Because any ultrasound device used to accomplish the disclosed goal in Kulow – impingement of ultrasonic waves on tissue – would not necessarily function to perform the methods recited in claims 26 and 29, the limitations recited in claims 26 and 29 are not inherently present in Kulow and Kulow does not anticipate these claims.

**C. Lewis**

Lewis teaches a device for cleaning the medullary canal and hip joint socket with liquid that is agitated with ultrasonic energy to enhance its cleaning capability. Col. 1, lines 1, line 46 to col. 2, line 4. More specifically, in the Lewis device, liquid travels through a transducer 14 and emerges from delivery ports 20 on an applicator tube 16 carrying ultrasonic energy to remove unwanted debris from a bone surface. "As the liquid flows across the unwanted particles of material that cling to and is [sic] interposed between the bone and the applicator tube 16, ultrasonic energy is liberated from the liquid, shocking, vibrating, and acting upon the unwanted particles, causing the unwanted particles to be dislodged from adherence to the bone structure." Col. 5, lines 56-64. Lewis is entirely unrelated to the use of ultrasound to promote wound healing and certainly does not teach or suggest that its disclosed device promotes wound healing. Rather, as clearly reflected in its title, Lewis is directed entirely to wound *cleaning*. Nothing in Lewis teachings that the cleaning solution used in the Lewis device or the ultrasonic energy contained therein has any benefits other than cleaning unwanted tissue and particles from bones surfaces.

Neither does the device disclosed in Lewis emit ultrasonic waves. Rather, Lewis merely teaches emission of a fluid that has been subjected to ultrasonic energy. It does not teach propagation of ultrasonic waves to contact a wound to promote healing thereof, as recited in claims 26 and 29, and thus does not anticipate these claims for at least these reasons.

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Finally, even assuming, *arguendo*, that the liquid used in the Lewis device could properly be characterized as “ultrasonic waves,” Lewis does not teach or suggest directing the liquid toward a surface in the body to reflect at least some of the ultrasonic waves off of the body surface and toward the wound such that the reflected waves contact and promote healing of the wound, as recited in claim 26. Rather, the liquid is impinged directly on the bone (the only arguable wound) to remove debris thereon. *See, e.g.*, col. 1, lines 57-58 (“the liquid is placed into direct contact with the surface of the wound or bone”); col. 2, lines 65-68 (“The method of the present invention comprehends flowing a cleaning liquid through an ultrasonic transducer and directly into the interior of a wound . . .”). Lewis thus does not anticipate claim 26 for this additional reason.

Neither Castel, Kulow, or Lewis teach or suggest the subject matter recited in independent claims 26 and 29. These claims are therefore allowable. Because none of the art relied upon by the Action anticipates independent claims 26 and 29, the art also does not anticipate claims 27 and 28, which depend from allowable claim 26, or claims 30-35, which depend from allowable claim 29. These dependent claims are therefore allowable for at least this reason.

## II. 35 U.S.C. § 103 Rejections

The Action rejects claims 26-37 under 35 U.S.C. § 103 as being unpatentable over Fox in view of Thomson or Pellico. The Action maintains that “Fox discloses an annular piezoelectric device used to deliver medicaments into the patient” and that Fox teaches using ultrasound in wound healing. Thus, the Action concludes, that it would have been obvious to place the Fox device over a wound to promote wound healing. Applicants traverse this rejection and request its withdrawal.

Claims 26, 29, and 36 are directed to methods of promoting healing of a wound. Fox fails to teach a method for healing a wound. While Fox describes in the Background of the Invention section background art relating to broad applications for ultrasonics in general, including improved wound healing, improved drug delivery, and “sound heating,” Fox, col. 1, line 38, it is in no way related to the methods of wound healing as contemplated by claims 26, 29, and 36 of the present invention.

Rather, the entire remainder of the disclosure of Fox relates to a device for and method of phonophoretically delivering medicaments across the skin, which is a completely different

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method from those recited in claims 26, 29, and 36. Fox discloses a disposable piezoelectric polymer bandage assembly containing a medicament. The piezoelectric polymer in the bandage assembly generates sonic vibrations that allegedly facilitate percutaneous delivery of drugs. Fox contains no disclosure that describes using its bandage in a method to heal wounds or that explains how this should be done, just as Fox contains no disclosure of how to use his device for "sound heating." Neither of these uses are even disclosed as objects of Fox's invention. *See* col. 1, lines 65-68 and col. 2, lines 1-12. The only use that Fox discloses for his device is the percutaneous delivery of medicaments. *See* col. 2, lines 15-28 (emphasis added):

It has now been found that the foregoing and related objects can be readily attained in a bandage assembly for percutaneous administration of a medicament. This assembly includes a bandage member having a cavity functionally opening on one surface thereof and a body element extending over the cavity and fabricated from a piezoelectric polymer. The bandage member has one surface adapted to be placed against the skin, and it has a medicament composition in the cavity. A pair of electrical contacts on the body element are disposed adjacent the opposite surfaces of the piezoelectric body element, and are connected to a sonic generator to generate sonic vibrations in the body element to induce percutaneous transfer of the medicament composition.

While Fox styles his product a "bandage," it is very clear from the specification and drawings of Fox that this term does not imply the presence of a wound, and does not imply that the Fox device is used in a method for treating a wound or accelerating wound healing. The Fox device is a "bandage" only in the sense that it adheres to the skin. Fox does not even disclose the presence of a wound anywhere on the patient to be treated, much less the presence of a wound sufficiently close to the "bandage" that any sonic emissions of the bandage would or could result in accelerated wound healing.

Fox therefore fails to disclose a method for promoting healing of a wound, as recited in claims 26, 29, and 36. The Action relies upon Thompson and Pellico as teaching the "use [of] a medicament to treat wounds." Action, p. 3. Apparently the Action's argument is that because Thompson and Pellico allegedly teach using medicine to heal wounds and because Fox teaches a device to drive medicines across the skin using ultrasound, it would have been obvious to use the device of Fox to administer the Thompson and Pellico wound-healing medicines and thereby promote wound healing by virtue of both the medicine itself and the vibrations used in the Fox bandage to drive the medicine into the skin. Applicants respectfully disagree.

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Pellico and Thompson et al. each relates exclusively to a medication for topical application on the skin. Pellico discloses an agar gel for coating a burn on the exterior of the skin so that the gel maintains a "fixed, tissue abutting relationship at the burn site." Col. 5, lines 1-3. Thompson et al. discloses an amino acid for treating skin conditions. As with Pellico, Thompson et al. teaches that its composition "is applied externally by direct contact with the skin surface to be treated." Col. 3, lines 30-31.

The Action maintains that the Fox device "is known to be used in the treatment of wounds *as seen for example in Pellico and Thompson et al.*" However, Pellico and Thompson are completely unrelated to drug delivery devices but rather teach manual application of the medicines onto the outer surface of the skin. Thus, contrary to the Action's assertion, neither Pellico nor Thompson teaches use of a device similar to that disclosed in Fox to apply its disclosed medication. Nor would it be obvious to combine the teachings of Fox and Pellico and/or Thompson.

Even assuming, *arguendo*, that Fox was directed toward wound healing, one of skill in the art would not be motivated to use the Fox device with the medicines disclosed in Pellico or Thompson. The Fox device is directed toward driving medication into the pores of and across the skin. Pellico and Thompson teach medicines for treatment of burns and skin disorders. These references disclose treatment by topical application of the medicines directly on the wound so as "to lightly cover the affected area of skin" (Thompson, col. 8, l. 14) or to form a "coating" on the exterior of a burn or other skin impairment (Pellico, col. 2, ll. 23-24). It would make no sense to use the Fox device with the medicines disclosed in Pellico and Thompson. The medicines disclosed in Pellico and Thompson are not intended to be driven into the skin as the Fox device would do. Rather, because they are for use on exposed wounds (i.e., damaged skin), they need only be applied to the outside of, not driven into, the skin to have their intended therapeutic effect.

Just as it would not be obvious to adapt the Fox device for use with the medicines of Pellico and Thompson, nor would it be obvious to apply the medicines of Pellico and Thompson with a device such as disclosed in Fox. As explained above, such a device is unnecessary for the Pellico and Thompson medicines to have their healing effect. Neither reference teaches application of its disclosed medicine by a special device or teaches that its medicine should be applied anywhere by directly to the exterior of the wound. Moreover, one of skill in the art

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would not subject a patient treated with the medicines of Pellico or Thompson to the detrimental effects of ultrasound (which would occur with use of the Fox device) when such exposure was unnecessary to the effectiveness of the medication. For at least this reason, it would not be obvious to combine the teachings of Fox with Thompson or Pellico and thus these references do not render independent claims 26, 29, and 36, or the claims that depend from these independent claims, obvious.

Moreover, Fox teaches positioning its device directly adjacent a target skin area and directing medicine directly into the skin using sonic vibrations. Nothing in Fox teaches or suggests directing the sonic vibrations (the only arguable "waves") and consequently the medicine anywhere but directly into the skin. Indeed, directing the vibrations, and thus driving the medicine, away from the target skin area (the alleged wound) would defeat the entire purpose of the device – to drive medicine directly into, and thereby focus the medicine on, the skin to be treated so that all of the medicine will reach the intended area. Thus, there is certainly no teaching or suggestion in Fox of at least:

- (a) directing the sonic vibrations (and thus the medicine) toward a surface of the body for reflecting at least some of the vibrations off of the body surface and toward the wound or that such reflected vibrations contact the wound for healing, as recited in claim 26; or
- (b) directing the vibrations (and thus the medicine) toward an area offset from the axis of a transducer or that such vibrations contact the wound for healing, as recited in claim 29.

The Action acknowledges this lack of disclosure in the references by relying upon the principle of inherency to conclude that the "reflection of the waves and the angular offset toward a wound would be inherent in the use of the [Fox] device on a patient in that both skin/tissue and bone present in the patient would inherently cause such reflections and change in direction of at least some of the ultrasonic waves." Action, p. 3.

Again, the Action's resort to the inherency doctrine is misplaced. The Fox device does not *necessarily function* in the manner recited in claims 26 and 29. The Fox device drives medication directly into the skin and thus the wave reflection (recited in claim 26) and the directed wave offset (recited in claim 29) likely would not, but certainly does not have to, occur as the Action maintains. Because the medicine and associated vibrations are focused directly



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onto the target skin area, no waves are available to be reflected off of a body surface and toward the wound. Rather, all of the alleged waves are directed, not reflected, toward the wound. Moreover, even assuming, *arguendo*, that wave reflection did occur with use of the Fox device, such waves would not necessarily be reflected toward a wound or to contact a wound so that the reflected waves promoted wound healing, as recited in claim 26. Similarly, even assuming, *arguendo*, that use of the Fox device resulted in waves being directed toward an area offset from a transducer axis, such waves would not necessarily contact the wound to promote healing, as recited in claim 29.

Because none of the cited references teach or suggest, either explicitly or inherently, (1) directing waves toward a surface of the body capable of reflecting ultrasonic waves and reflection of waves off of that body surface toward the wound so that the reflected waves contact and promote healing of the wound or (2) directing waves in a direction offset from the transducer axis so that such waves contact a wound and promote healing thereof, none of the cited references alone or in combination teach or suggest the claimed subject matter recited in claims 26 and 29, and these claims are allowable for these additional reasons. Because independent claims 26 and 29 are allowable, so too are claims 27 and 28, which depend from allowable claim 26, and claims 30-35, which depend from allowable claim 29.

With respect to claim 36, Fox further fails to teach or suggest emitting ultrasonic waves through an annularly-shaped operative surface such that at least some of the waves propagate through tissue to contact the wound, as recited in claim 36. The only arguable annularly-shaped operative surface disclosed in Fox is annular element 52, disclosed in Figures 3 and 4. The embodiment of Figures 3 and 4 discloses annular element 52 and body elements 54, 55, all of which comprise a piezoelectric polymer. Elements 52, 54, and 55 are connected to a sonic generator, which causes these elements to vibrate. Annular element 52 vibrates parallel to the skin surface to stretch or tension the skin to facilitate transfer of medicine into the skin. Col. 2, lines 39-46; col. 3, lines 5-7; col. 5, lines 2-6 and lines 16-19. Non-annular elements 54 and 55, in turn, vibrate perpendicular to the skin surface to drive the medication 58 into the skin.

Fox does not teach or suggest that annular element 52 directs ultrasonic waves towards or into the skin to generate compression waves that propagate through tissue and contact a wound, as required by claim 36. Nor could annular element 52 propagate waves in that fashion through its vibration back and forth on (not towards and away from) the skin surface. Furthermore, even

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if annular element 52 could emit ultrasonic waves towards the skin, nothing in Fox teaches that such waves would be of a frequency to propagate through tissue.

Because Fox fails to teach or suggest emitting ultrasonic waves through an annularly-shaped operative surface such that at least some of the waves propagate through tissue to contact the wound, it cannot render obvious claim 36 for this additional reason. Claim 36 and claim 37, which depends from claim 36, are allowable.

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**CONCLUSION**

Applicants respectfully submit that claims 26-37 are in condition for immediate allowance, and request early notification to that effect. If any issues remain to be resolved, the Examiner is respectfully requested to contact the undersigned at 404.815.6389 to arrange for a telephone interview prior to issuance of a final Office action.

Respectfully submitted,



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